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APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. 2039 10/647,372 08/25/2003 Edward H. Overstreet AB-362U EXAMINER 23845 7590 07/12/2005 ADVANCED BIONICS CORPORATION ALTER, ALYSSA M 25129 RYE CANYON ROAD ART UNIT PAPER NUMBER VALENCIA, CA 91355

DATE MAILED: 07/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

U.S. Patent and Trademark Office PTOL-326 (Rev. 1-04) Office Ac	ction Summary F	Part of Paper No./Mail Date 07072005
Attachment(s) 1) ⊠ Notice of References Cited (PTO-892) 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) ⊠ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 12/22/03 & 8/16/04.	4) Interview Summar Paper No(s)/Mail [5) Notice of Informal 6) Other:	
Attachment(s)		
* See the attached detailed Office action for a list of the certified copies not received.		
application from the International Bureau (PCT Rule 17.2(a)).		
3. Copies of the certified copies of the priority documents have been received in this National Stage		
2. Certified copies of the priority documents have been received in Application No		
1. Certified copies of the priority documents have been received.		
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of:		
Priority under 35 U.S.C. § 119		
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.		
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).		
10)⊠ The drawing(s) filed on <u>25 August 2003</u> is/are: a)⊠ accepted or b)□ objected to by the Examiner.		
9)⊠ The specification is objected to by the Examiner.		
Application Papers		
8) Claim(s) are subject to restriction and/or election requirement.		
7) Claim(s) is/are objected to.		
6)⊠ Claim(s) <u>1-20</u> is/are rejected.	·	
5) Claim(s) is/are allowed.		
4a) Of the above claim(s) is/are withdrawn from consideration.		
4)⊠ Claim(s) <u>1-20</u> is/are pending in the application.		
Disposition of Claims		
closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.		
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is		
	action is non-final.	
1) Responsive to communication(s) filed on 25 A	ugust 2003	
Status		
THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).		
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) FROM		
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply		
	Alyssa M. Alter	3762
Office Action Summary	Examiner	Art Unit
	10/647,372	OVERSTREET, EDWARD H.
	Application No.	Applicant(s)

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 1. Claims 1-2 and 6-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Carter et al. (US 6,205,360). Carter et al. discloses a multi-channel cochlear implant, consisting of an implanted electrode array, an implanted receiver/stimulator unit (RSU) and an externally worn speech processor. "For each implantee, it is necessary to set the dynamic range of the stimulus pulses presented by the electrode array in order to optimally and comfortably enhance speech perception by the implantee. The dynamic range is generally set between two parameters—the threshold level (T), being the minimum amount of electrical stimulation that is required to elicit a perceived sound from the implantee, and the comfort (C) level, defined as the maximum amount of electrical stimulation which can be applied before the patient reports discomfort. The T and C levels typically vary for each channel in a multichannel implant" (col. 1, lines 24-34). The comfort level, "C", is also commonly referred to as "M". In the Applicant's specification on page 4, paragraph 11, the applicant discloses that the "T" and "M" levels, a.k.a., iso-loudness contours.

Figure 3 displays the procedure for determining the T and C levels. "After startup 31 the system enters telemetry mode 32 as the information regarding the electrical

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activity of the auditory nerve and the stapedius muscle are to be sent to the speech processor. The T levels are then calculated for each channel and stored in the T&C level table at step 33. Using the T levels as a starting point the C levels are then derived for each channel and similarly stored in the T&C level table 34. The cochlear implant then returns to normal operation 36 using the newly defined dynamic range. The T&C level setting program then ends 37"(col. 7, lines 7-17).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 1. Claims 10-15 and 18 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Carter et al. (US 6,205,360) in view of McDermott et al. (US 5,597,380). According to Carter et al., "once the T levels have been calculated for each stimulation channel those levels are used as a starting point for calculating the C levels (col. 6, lines 60-62). Since Carter et al. utilizes the T values as a starting point for calculating the C levels, the examiner considers the T and C levels to have a linear relationship.

In the alternative, Carter et al. discloses the device substantially as claimed but fails to teach the linear correlation between the T and M levels. McDermott et al. teaches that it is known "that the relationship between perceived loudness and the

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electrical level of the causative stimulation can be approximately by power function. Thus loudness (on a log scale) is directly proportional to the log of the amplitude (the log of a power function is a linear function)" as set forth in column 5, lines 7-12. The examiner considers the perceived loudness to be the comfort level and the electrical stimulation to be the threshold stimulus. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the T and M levels as taught by Carter et al. to have a linear correlation as taught by McDermott et al., since it was known in the art that the T levels can be utilized to determine the M levels.

As to claims 10, 12-15 and 18, the Applicant states on page 5, paragraph 14, "M iso-loudness contours (or iso-neural contours)". Therefore, the examiner considers iso-neural contors to be iso-loudness contours. In claims 10, 12, 15 and 18, the examiner considers the determined iso-neural response contour to be the T level and the iso-loudness contour to be the M level. 3-5, 10-15 and 18

2. Claims 3-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carter et al. (US 6,205,360). Carter et al. discloses the claimed invention but does not disclose expressly the sounds to be tones, noises or speech. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the sounds as taught by Carter et al., with the tones, noises or speech, because Applicant has not disclosed the tones, noises or speech provides an advantage, is used for a particular purpose, or solve a stated problem. One of ordinary skill in the art, furthermore, would have expected the Applicant's invention to perform equally well with

sounds as taught by Carter et al., because all of the sounds could be received by the speech processor.

Therefore, it would have been an obvious matter of design choice to modify sounds to obtain the invention as specified in the claim(s).

3. Claims 16-17 and 19-20 are rejected under 35 U.S.C. 103(a) as obvious over the modified Carter et al. (US 6,205,360), as applied to claims 10-15 and 18 above. The modified Carter et al. discloses the claimed invention except for the first iso-loudness contour as the M iso-loudness contour and the second iso-loudness contour as the T iso-loudness contour. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the T iso-loudness contour as the first and M iso-loudness contour as the second iso-loudness countours as taught by the modified Carter et al. with M iso-loudness contour as the first and T iso-loudness contour as the second since it was known in the art that that T and M possess a linear correlation, and thus a direct correlation. Therefore, adjusting the first and second iso-loudness contours would not alter the relationship between T and M.

As to claims 19-20, the modified Carter et al. discloses the claimed invention except for the pulse width ranges. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the pulse widths, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233 (see MPEP 2244.05).

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4. Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carter et al. (US 6,205,360) in view of McDermott et al. (US 5,597,380). Carter et al. discloses the claimed invention except for a virtual channel or skipping a channel. McDermott et al. teaches that it is known to that depending upon the corresponding sound signals, there may be fewer than six or no channels stimulated in a given period, if there is no sound, or sound which is very narrow spectrally as set forth in column 3, lines 23-26. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the channels as taught by Carter et al. with the channels as taught by McDermott et al., in order to modify the cochlear implant to meet specific patients needs.

Specification

- 1. The disclosure is objected to because of the following informalities: ©) on page 11, paragraph 43 and page 12, paragraph 45. The examiner recommends changing "©)" to --(C)—. Appropriate correction is required.
- 2. The use of the trademarks Clarion®, CII Bionic Ear™, HiRes90K, Advanced Bionics® and Clarion ICS has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology. Capitalize each letter of the word in the bracket or include a proper trademark symbol, such as ™ or ® following the word.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

Conclusion

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The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- Peeters (US 6,778,858 B1) discloses a cochlear implant. 1.
- 2. Faltys et al. (US 6,157,861) discloses a self-adjusting cochlear implant system and method for fitting same.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alyssa M. Alter whose telephone number is (571) 272-4939. The examiner can normally be reached on M-F 9am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free).

Alyssa M Alter
Examiner
Art Unit 3762

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